COMMONWEALTH OF VIRGINIA DIVISION OF PURCHASES AND SUPPLY 1111 E. BROAD STREET P. O. BOX 1199 RICHMOND, VIRGINIA 23218-1199

NOTICE OF AWARD

	
1.	DATEJanuary 5, 2012
2.	COMMODITY NAMETest Kits, T4, TSH, CAH & Equipment
3.	CONTRACT NUMBERE194-1376
4.	CONTRACT PERIODJanuary 1, 2012 through December 31, 2014
5.	SUPERSEDES E194-379-11
6.	AUTHORIZED USERDepartment of General Services, Division of Consolidated LaboratoryServices (DCLS)
7.	CONTRACTOR DUNS NUMBER
8.	CONTRACTOR PerkinElmer Health Sciences Paul Vetter, Account Manager 710 Bridgeport Avenue Shelton, CT 06484 Phone: 301-706-2723 Fax: 928-563-8895 Email: paul.vetter@perkinelmer.com DUNS Number: 13-2010856 eVA ID Number: E5348 SCC Number: F1608787
9.	TERMSNet 30
10.	DELIVERY14 Days ARO
11.	MINIMUM ORDER\$100.00
12.	FURTHER CONTRACT INFORMATION CONTACTTina M. Rodriguez, CPPB, VCO Phone: (804) 786-1603 Fax: (804) 786-5712 Email: tina.rodriguez@dgs.virginia.gov
13.	ADDITIONAL COPIES OF CONTRACTS AND ANY ASSOCIATED CONTRACT CHANGES MAY BE VIEWED AND PRINTED AT THE DPS WEBSITE: www.eva.virginia.gov
14.	NOTICE TO DCLS: This contract is the result of a competitive bid program and its use is

<u>Mandatory</u> (unless otherwise indicated in item 6 above) in the purchase of any commodity listed herein. If the commodity or services available under this contract cannot be used by the agency, a request to purchase other goods or services of a similar nature shall be submitted to the appropriate DGS/DPS contract/purchase officer for approval. A complete and factual written

Test Kits, T4, TSH, CAH & Equipment Contract Number E194-1376 Page 2 of 21 1/5/2012

- justification is necessary to support the request. Refer to Section 13.7a of the Agency Procurement and Surplus Property Manual.
- 15. Note: This public body does not discriminate against faith-based organizations in accordance with the *Code of Virginia*, § 2.2-4343.1 or against a bidder or offeror because of race, religion, color, sex, national origin, age, disability, or any other basis prohibited by state law relating to discrimination in employment.

By: /s/ Tina M. Rodriguez, CPPB, VCO Statewide Contract Officer

INSTRUCTIONS

- 1. <u>ORDERS</u>: Unless otherwise instructed by the Division of Purchases and Supply, DCLS will order items through eVA.
- 2. The applicable state contract number, federal employer identification number (FEI), and item number (for itemized contracts) must be shown on each purchase order and copy, each facsimile transmission or given verbally when telephonic orders are placed.
- 3. Inspection on delivery and approval of vendor's invoice is the responsibility of the receiving state agency.
- 4. Any complaint as to quality, faulty or delinquent delivery, or violation of contract provisions by contractor shall be reported to the Division of Purchases and Supply for handling with the contractor. Preprinted forms (DGS-41-024), by which to facilitate the notification of the contractor and this office of complaints, are available from the Division of Purchases and Supply (804-225-4045) or online at the following web address: http://www.eva.virginia.gov/buyers/index.htm.
- 5. <u>RENEWALS</u>. <u>Three (3)</u>, one-year optional renewals remain. The decision as to whether to exercise the next renewal option will be made by the contract officer approximately three to four months in advance of the expiration date of the current term.

NOTICE OF AWARD Contract Number E194 - 1376

Contract Number: E194-1376

Document ID: 1376 Title: Test Kits, T4, TSH, CAH & Equipment

Print Date: 1/4/2012

Procurement Folder: 72667 Procurement Type: Complex IFB
Effective Begin Date: 1/4/2012 Expiration Date: 12/31/2014
Minimum Order Amount: \$100.00 Maximum Order Amount: \$0.00

On Behalf Of Name: Tina Rodriguez (Mizelle) Phone: (804) 786-1603

Email: tina.rodriguez@dgs.virginia.gov

Preparer Name: Tina Rodriguez (Mizelle) Phone: (804) 786-1603

Email: tina.rodriguez@dgs.virginia.gov

Description: Test Kits, T4, TSH, CAH & Equipment for DCLS

Created By: tmizelle1 Modified By: tmizelle1
Created On: 2012-01-04 Modified On: 2012-01-04

Contract Administrator Contact Information

Tina M. Rodriguez, CPPB, VCO Phone: (804) 786-1603

Email: tina.rodriguez@dgs.virginia.gov

Renewal Periods

Line Number	Renewal Period Length	Renewal Period Unit	Effective Date	Expiration Date	Notification Days (Prior to Expiration)
1	1	Years	1/1/2015	12/31/2015	90
2	1	Years	1/1/2016	12/31/2016	90
3	1	Years	1/1/2017	12/31/2017	90

Authorized Departments

Department of General Services, Division of Consolidated Laboratory Services, Newborn Screening Lab, Thomas M. Hickey, PhD, Newborn Screening Lab Group Manager, 600 North 5th Street, Richmond, VA 23219

Vendor Ordering Information

Legal Name: PerkinElmer Health Sciences, Inc
Address: 710 Bridgeport Avenue, Shelton CT
Contact E

06484

MA Number: E194 - 1376 Fax Number: 928-563-8895

Contact Name: Paul Vetter, Area Manager Contact Email: paul.vetter@perkinelmer.com

Contact Phone: 301-706-2723

Commodity Lines

Line: 1

Line Type: Item NIGP Code: 26936

Description: T4 (Thyroxine) Reagent Kits, Equipment and Consumables - 112 wells per kit. DCLS

estimated number of tests = 230,000

Unit Price: \$2,380.00 Part Number: 3302-001U Unit of Measure: Each / Kit Delivery: 14 days ARO

Free On Board Name: FOB Destination-Freight Prepaid

Ship Location:

Shipping Location: DGS - DIVISION OF CONSOLIDATED LABORATORY SERVICES

Shipping Street Address 1: 600 N. 5th Street, Richmond, VA 23219

Shipping Instructions: ATTN: Thomas M. Hickey, PhD, Newborn Screening Group Manager

Line: 2

Line Type: Item
NIGP Code: 26936

Description: TSH (Thyroid Stimulating Hormone) Reagent Kits, Equipment and Consumables - 112 wells

per kit. DCLS estimated number of tests = 50,000

Unit Price: \$2,270.00 Part Number: 3301-001U Unit of Measure: Each / Kit Delivery: 14 days ARO

Free On Board Name: FOB Destination-Freight Prepaid

Ship Location:

Shipping Location: DGS - DIVISION OF CONSOLIDATED LABORATORY SERVICES

Shipping Street Address 1: 600 N. 5th Street, Richmond, VA 23219

Shipping Instructions: ATTN: Thomas M. Hickey, PhD, Newborn Screening Group Manager

Line: 3

Line Type: Item NIGP Code: 26936

Description: CAH (Congenital Adrenal Hyperplasia) Reagent Kits, Equipment and Consumables - 112

wells per kit. DCLS estimated number of tests = 230,000

Unit Price: \$2,460.00 Part Number: 3305-001U Unit of Measure: Each / Kit Delivery: 14 days ARO

Free On Board Name: FOB Destination-Freight Prepaid

Ship Location:

Shipping Location: DGS - DIVISION OF CONSOLIDATED LABORATORY SERVICES

Shipping Street Address 1: 600 N. 5th Street, Richmond, VA 23219

Shipping Instructions: ATTN: Thomas M. Hickey, PhD, Newborn Screening Group Manager

Consumables Supplied at No Charge to DCLS

Unit of Measure	Part Number	<u>Description</u>	Unit Price
Kit	1235-402	Disposable Pipette Tips (960 tips/package)	N/C
Kit	3060-0010	GSP Test Kit	N/C
Kit	4080-0010	GSP Wash Concentrate, 1000 ml	N/C
Kit	3304-0010	DELFIA Inducer (12 x 500 ml)	N/C
Kit	2021-4010	50 ul Pipette Tip	N/C

General Terms and Conditions

TERMS AND CONDITIONS

The General and Special Terms and Conditions of the Commonwealth of Virginia are to be considered mandatory. Any changes and/or exceptions to these Terms and Conditions or modifications will not be accepted and shall render your bid non-responsive.

GENERAL TERMS AND CONDITIONS

A. VENDORS MANUAL: This solicitation is subject to the provisions of the Commonwealth of Virginia Vendors Manual and any changes or revisions thereto, which are hereby incorporated into this contract in their entirety. The procedure for filing contractual claims is in section 7.19 of the Vendors Manual. A copy of the manual is normally available for review at the purchasing office and is accessible on the Internet at www.eva.virginia.gov under "Vendors Manual" on the "Vendor" tab.

B. APP. LAWS AND COURTS

APPLICABLE LAWS AND COURTS: This solicitation and any resulting contract shall be governed in all respects by the laws of the Commonwealth of Virginia and any litigation with respect thereto shall be brought in the courts of the Commonwealth. The agency and the contractor are encouraged to resolve any issues in controversy arising from the award of the contract or any contractual dispute using Alternative Dispute Resolution (ADR) procedures (Code of Virginia, § 2.2-4366). ADR procedures are described in Chapter 9 of the Vendors Manual. The contractor shall comply with all applicable federal, state and local laws, rules and regulations.

C. ANTI-DISCRIMINATION:

ANTI-DISCRIMINATION: By submitting their (bids/proposals), (bidders/offerors) certify to the Commonwealth that they will conform to the provisions of the Federal Civil Rights Act of 1964, as amended, as well as the Virginia Fair Employment Contracting Act of 1975, as amended, where applicable, the Virginians With Disabilities Act, the Americans With Disabilities Act and § 2.2-4311 of the Virginia Public Procurement Act (VPPA). If the award is made to a faith-based organization, the organization shall not discriminate against any recipient of goods, services, or disbursements made pursuant to the contract on the basis of the recipient's religion, religious belief, refusal to participate in a religious practice, or on the basis of race, age, color, gender or national origin and shall be subject to the same rules as other organizations that contract with public bodies to account for the use of the funds

provided; however, if the faith-based organization segregates public funds into separate accounts, only the accounts and programs funded with public funds shall be subject to audit by the public body. (Code of Virginia, § 2.2-4343.1E). In every contract over \$10,000 the provisions in 1. and 2. below apply: 1. During the performance of this contract, the contractor agrees as follows: a. The contractor will not discriminate against any employee or applicant for employment because of race, religion, color, sex, national origin, age, disability, or any other basis prohibited by state law relating to discrimination in employment, except where there is a bona fide occupational qualification reasonably necessary to the normal operation of the contractor. The contractor agrees to post in conspicuous places, available to employees and applicants for employment, notices setting forth the provisions of this nondiscrimination clause. b. The contractor, in all solicitations or advertisements for employees placed by or on behalf of the contractor, will state that such contractor is an equal opportunity employer. c. Notices, advertisements and solicitations placed in accordance with federal law, rule or regulation shall be deemed sufficient for the purpose of meeting these requirements. 2. The contractor will include the provisions of 1. above in every subcontract or purchase order over \$10,000, so that the provisions will be binding upon each subcontractor or vendor.

D.ETHICS IN PUBLIC CONTRACTING

ETHICS IN PUBLIC CONTRACTING: By submitting their (bids/proposals), (bidders/offerors) certify that their (bids/proposals) are made without collusion or fraud and that they have not offered or received any kickbacks or inducements from any other (bidder/offeror), supplier, manufacturer or subcontractor in connection with their (bid/proposal), and that they have not conferred on any public employee having official responsibility for this procurement transaction any payment, loan, subscription, advance, deposit of money, services or anything of more than nominal value, present or promised, unless consideration of substantially equal or greater value was exchanged.

E. IMMIGRATION REFORM

IMMIGRATION REFORM AND CONTROL ACT OF 1986: By entering into a written contract with the Commonwealth of Virginia, the Contractor certifies that the Contractor does not, and shall not during the performance of the contract for goods and services in the Commonwealth, knowingly employ an unauthorized alien as defined in the federal Immigration Reform and Control Act of 1986.

F. DEBARMENT STATUS

DEBARMENT STATUS: By submitting their (bids/proposals), (bidders/offerors) certify that they are not currently debarred by the Commonwealth of Virginia from submitting bids or proposals on contracts for the type of goods and/or services covered by this solicitation, nor are they an agent of any person or entity that is currently so debarred.

G. ANTITRUST

ANTITRUST: By entering into a contract, the contractor conveys, sells, assigns, and transfers to the Commonwealth of Virginia all rights, title and interest in and to all causes of action it may now have or hereafter acquire under the antitrust laws of the United States and the Commonwealth of Virginia, relating to the particular goods or services purchased or acquired by the Commonwealth of Virginia under said contract.

H. MANDATORY USE OF STATE FORM

MANDATORY USE OF STATE FORM AND TERMS AND CONDITIONS FOR IFB's: Failure to submit a bid on the official state form provided for that purpose shall be a cause for rejection of the bid. Modification of or additions to any portion of the Invitation for Bids may be cause for rejection of the bid; however, the Commonwealth reserves the right to decide, on a case

by case basis, in its sole discretion, whether to reject such a bid as nonresponsive. As a precondition to its acceptance, the Commonwealth may, in its sole discretion, request that the bidder withdraw or modify nonresponsive portions of a bid which do not affect quality, quantity, price, or delivery. No modification of or addition to the provisions of the contract shall be effective unless reduced to writing and signed by the parties.

I. CLARIFICATION OF TERMS

CLARIFICATION OF TERMS: If any prospective (bidder/offeror) has questions about the specifications or other solicitation documents, the prospective (bidder/offeror) should contact the buyer whose name appears on the face of the solicitation no later than five working days before the due date. Any revisions to the solicitation will be made only by addendum issued by the buyer.

K. PRECEDENCE OF TERMS

PRECEDENCE OF TERMS: The following General Terms and Conditions VENDORS MANUAL, APPLICABLE LAWS AND COURTS, ANTI-DISCRIMINATION, ETHICS IN PUBLIC CONTRACTING, IMMIGRATION REFORM AND CONTROL ACT OF 1986, DEBARMENT STATUS, ANTITRUST, MANDATORY USE OF STATE FORM AND TERMS AND CONDITIONS, CLARIFICATION OF TERMS, PAYMENT shall apply in all instances. In the event there is a conflict between any of the other General Terms and Conditions and any Special Terms and Conditions in this solicitation, the Special Terms and Conditions shall apply.

L. QUALIFICATIONS

QUALIFICATIONS OF (BIDDERS/OFFERORS): The Commonwealth may make such reasonable investigations as deemed proper and necessary to determine the ability of the (bidder/offeror) to perform the services/furnish the goods and the (bidder/offeror) shall furnish to the Commonwealth all such information and data for this purpose as may be requested. The Commonwealth reserves the right to inspect (bidder's/offeror's) physical facilities prior to award to satisfy questions regarding the (bidder's/offeror's) capabilities. The Commonwealth further reserves the right to reject any (bid/proposal) if the evidence submitted by, or investigations of, such (bidder/offeror) fails to satisfy the Commonwealth that such (bidder/offeror) is properly qualified to carry out the obligations of the contract and to provide the services and/or furnish the goods contemplated therein.

M. TESTING AND INSPECTION

TESTING AND INSPECTION: The Commonwealth reserves the right to conduct any test/inspection it may deem advisable to assure goods and services conform to the specifications.

N. ASSIGNMENT OF CONTRACT

ASSIGNMENT OF CONTRACT: A contract shall not be assignable by the contractor in whole or in part without the written consent of the Commonwealth.

O. CHANGES TO THE CONTRACT

Changes can be made to the contract in any of the following ways: 1. The parties may agree in writing to modify the scope of the contract. An increase or decrease in the price of the contract resulting from such modification shall be agreed to by the parties as a part of their written agreement to modify the scope of the contract. 2. The Purchasing Agency may order changes

within the general scope of the contract at any time by written notice to the contractor. Changes within the scope of the contract include, but are not limited to, things such as services to be performed, the method of packing or shipment, and the place of delivery or installation. The contractor shall comply with the notice upon receipt. The contractor shall be compensated for any additional costs incurred as the result of such order and shall give the Purchasing Agency a credit for any savings. Said compensation shall be determined by one of the following methods: a. By mutual agreement between the parties in writing; or b. By agreeing upon a unit price or using a unit price set forth in the contract, if the work to be done can be expressed in units, and the contractor accounts for the number of units of work performed, subject to the Purchasing Agency's right to audit the contractor's records and/or to determine the correct number of units independently; or c. By ordering the contractor to proceed with the work and keep a record of all costs incurred and savings realized. A markup for overhead and profit may be allowed if provided by the contract. The same markup shall be used for determining a decrease in price as the result of savings realized. The contractor shall present the Purchasing Agency with all vouchers and records of expenses incurred and savings realized. The Purchasing Agency shall have the right to audit the records of the contractor as it deems necessary to determine costs or savings. Any claim for an adjustment in price under this provision must be asserted by written notice to the Purchasing Agency within thirty (30) days from the date of receipt of the written order from the Purchasing Agency. If the parties fail to agree on an amount of adjustment, the question of an increase or decrease in the contract price or time for performance shall be resolved in accordance with the procedures for resolving disputes provided by the Disputes Clause of this contract or, if there is none, in accordance with the disputes provisions of the Commonwealth of Virginia Vendors Manual. Neither the existence of a claim nor a dispute resolution process, litigation or any other provision of this contract shall excuse the contractor from promptly complying with the changes ordered by the Purchasing Agency or with the performance of the contract generally.

P. DEFAULT

DEFAULT: In case of failure to deliver goods or services in accordance with the contract terms and conditions, the Commonwealth, after due oral or written notice, may procure them from other sources and hold the contractor responsible for any resulting additional purchase and administrative costs. This remedy shall be in addition to any other remedies which the Commonwealth may have.

Q. TAXES

TAXES: Sales to the Commonwealth of Virginia are normally exempt from State sales tax. State sales and use tax certificates of exemption, Form ST-12, will be issued upon request. Deliveries against this contract shall usually be free of Federal excise and transportation taxes. The Commonwealth's excise tax exemption registration number is 54-73-0076K.

R. USE OF BRAND NAMES

USE OF BRAND NAMES: Unless otherwise provided in this solicitation, the name of a certain brand, make or manufacturer does not restrict (bidders/offerors) to the specific brand, make or manufacturer named, but conveys the general style, type, character, and quality of the article desired. Any article which the public body, in its sole discretion, determines to be the equivalent of that specified, considering quality, workmanship, economy of operation, and suitability for the purpose intended, shall be accepted. The (bidder/offeror) is responsible to clearly and

specifically identify the product being offered and to provide sufficient descriptive literature, catalog cuts and technical detail to enable the Commonwealth to determine if the product offered meets the requirements of the solicitation. This is required even if offering the exact brand, make or manufacturer specified. Normally in competitive sealed bidding only the information furnished with the bid will be considered in the evaluation. Failure to furnish adequate data for evaluation purposes may result in declaring a bid nonresponsive. Unless the (bidder/offeror) clearly indicates in its (bid/proposal) that the product offered is an equivalent product, such (bid/proposal) will be considered to offer the brand name product referenced in the solicitation.

S.TRANSPORTATION AND PACKAGING

TRANSPORTATION AND PACKAGING: By submitting their (bids/proposals), all (bidders/offerors) certify and warrant that the price offered for FOB destination includes only the actual freight rate costs at the lowest and best rate and is based upon the actual weight of the goods to be shipped. Except as otherwise specified herein, standard commercial packaging, packing and shipping containers shall be used. All shipping containers shall be legibly marked or labeled on the outside with purchase order number, commodity description, and quantity.

T. INSURANCE (1 of 3)

INSURANCE (part 1 of 3): By signing and submitting a bid or proposal under this solicitation, the bidder or offeror certifies that if awarded the contract, it will have the following insurance coverage at the time the contract is awarded. For construction contracts, if any subcontractors are involved, the subcontractor will have workers' compensation insurance in accordance with §§ 2.2-4332 and 65.2-800 et seq. of the Code of Virginia. The bidder or offeror further certifies that the contractor and any subcontractors will maintain these insurance coverage during the entire term of the contract and that all insurance coverage will be provided by insurance companies authorized to sell insurance in Virginia by the Virginia State Corporation Commission. (continued in part 2)

T. INSURANCE (2 of 3)

INSURANCE (part 2 of 3) MINIMUM INSURANCE COVERAGES AND LIMITS REQUIRED FOR MOST CONTRACTS: 1) Workers' Compensation - Statutory requirements and benefits. Coverage is compulsory for employers of three or more employees, to include the employer. Contractors who fail to notify the Commonwealth of increases in the number of employees that change their workers' compensation requirements under the Code of Virginia during the course of the contract shall be in noncompliance with the contract. 2). Employer's Liability - \$100,000. 3) Commercial General Liability - \$1,000,000 per occurrence. Commercial General Liability is to include bodily injury and property damage, personal injury and advertising injury, products and completed operations coverage. The Commonwealth of Virginia must be named as an additional insured and so endorsed on the policy 4). Automobile Liability - \$1,000,000 per occurrence. (Only used if motor vehicle is to be used in the contract.). (continued in part 3)

T. INSURANCE (3 of 3)

INSURANCE (part 3 of 3): NOTE: In addition, various Professional Liability/Errors and Omissions coverage are required when soliciting those services as follows: Profession/Service/Limits, Accounting /\$1,000,000 per occurrence, \$3,000,000 aggregate Architecture/\$2,000,000 per occurrence, \$6,000,000 aggregate, Asbestos Design, Inspection or Abatement Contractors/

\$1,000,000 per occurrence, \$3,000,000 aggregate, Health Care Practitioner (to include Dentists, Licensed Dental, Hygienists, Optometrists, Registered or Licensed, Practical Nurses, Pharmacists, Physicians, Podiatrists, Chiropractors, Physical Therapists, Physical ,Therapist Assistants, Clinical Psychologists, Clinical Social Workers, Professional Counselors, Hospitals, or Health Maintenance Organizations.) \$1,750,000 per occurrence, \$3,000,000 aggregate, (Limits increase each July 1 through fiscal year 2008, as follows: July 1, 2005 - \$1,800,000, July 1, 2006 - \$1,850,000, July 1, 2007 - \$1,925,000, July 1, 2008 - \$2,000,000. This complies with \$8.01-581.15 of the Code of Virginia. Insurance/Risk Management /\$1,000,000 per occurrence, \$3,000,000 aggregate, Landscape/Architecture/\$1,000,000 per occurrence, \$1,000,000 aggregate. Professional Engineer/\$2,000,000 per occurrence, \$6,000,000 aggregate, Surveying/\$1,000,000 per occurrence, \$1,000,000 per occurrence, \$1,000,000 aggregate

U. ANNOUNCEMENT OF AWARD

ANNOUNCEMENT OF AWARD: Upon the award or the announcement of the decision to award a contract over \$50,000, as a result of this solicitation, the purchasing agency will publicly post such notice on the DGS/DPS eVA website (www.eva.virginia.gov) for a minimum of 10 days.

V. DRUG-FREE WORKPLACE

DRUG-FREE WORKPLACE: During the performance of this contract, the contractor agrees to (i) provide a drug-free workplace for the contractor's employees; (ii) post in conspicuous places, available to employees and applicants for employment, a statement notifying employees that the unlawful manufacture, sale, distribution, dispensation, possession, or use of a controlled substance or marijuana is prohibited in the contractor's workplace and specifying the actions that will be taken against employees for violations of such prohibition; (iii) state in all solicitations or advertisements for employees placed by or on behalf of the contractor that the contractor maintains a drug-free workplace; and (iv) include the provisions of the foregoing clauses in every subcontract or purchase order of over \$10,000, so that the provisions will be binding upon each subcontractor or vendor. For the purposes of this section, "drug-free workplace" means a site for the performance of work done in connection with a specific contract awarded to a contractor, the employees of whom are prohibited from engaging in the unlawful manufacture, sale, distribution, dispensation, possession or use of any controlled substance or marijuana during the performance of the contract.

W. NONDISCRIMINATION

NONDISCRIMINATION OF CONTRACTORS: A bidder, offeror, or contractor shall not be discriminated against in the solicitation or award of this contract because of race, religion, color, sex, national origin, age, disability, faith-based organizational status, any other basis prohibited by state law relating to discrimination in employment or because the bidder or offeror employs ex-offenders unless the state agency, department or institution has made a written determination that employing ex-offenders on the specific contract is not in its best interest. If the award of this contract is made to a faith-based organization and an individual, who applies for or receives goods, services, or disbursements provided pursuant to this contract objects to the religious character of the faith-based organization from which the individual receives or would receive the goods, services, or disbursements, the public body shall offer the individual, within a reasonable period of time after the date of his objection, access to equivalent goods, services, or

disbursements from an alternative provider.

X. eVA REGISTRATION

eVA BUSINESS-TO-GOVERNMENT VENDOR REGISTRATION: The eVA Internet electronic procurement solution, website portal www.eVA.virginia.gov, streamlines and automates government purchasing activities in the Commonwealth. The eVA portal is the gateway for vendors to conduct business with state agencies and public bodies. All vendors desiring to provide goods and/or services to the Commonwealth shall participate in the eVA Internet eprocurement solution either through the eVA Basic Vendor Registration Service or eVA Premium Vendor Registration Service. All bidders or offerors must register in eVA and pay the Vendor Transaction Fees specified below; failure to register will result in the bid/proposal being rejected. Effective July 1, 2011, vendor registration and registration-renewal fees have been discontinued. Registration options are as follows: a. eVA Basic Vendor Registration Service: eVA Basic Vendor Registration Service includes electronic order receipt, vendor catalog posting, on-line registration, electronic bidding, and the ability to research historical procurement data available in the eVA purchase transaction data warehouse. b. eVA Premium Vendor Registration Service: eVA Premium Vendor Registration Service includes all benefits of the eVA Basic Vendor Registration Service plus automatic email or fax notification of solicitations and amendments. Vendor transaction fees are determined by the date the original purchase order is issued and are as follows: a. For orders issued prior to August 16, 2006, the Vendor Transaction Fee is 1%, capped at a maximum of \$500 per order. b. For orders issued August 16, 2006 thru June 30, 2011, the Vendor Transaction Fee is: (i) DMBE-certified Small Businesses: 1%, capped at \$500 per order. (ii) Businesses that are not DMBE-certified Small Businesses: 1%, capped at \$1,500 per order. c. For orders issued July 1, 2011 thru June 30, 2012, the Vendor Transaction Fee is: (i) DMBE-certified Small Businesses: 0.75%, capped at \$500 per order. (ii) Businesses that are not DMBE-certified Small Businesses: 0.75%, capped at \$1,500 per order, d. For orders issued July 1, 2012 and after, the Vendor Transaction Fee is: (i) DMBEcertified Small Businesses: 1%, capped at \$500 per order. (ii) Businesses that are not DMBEcertified Small Businesses: 1%, capped at \$1,500 per order. The specified vendor transaction fee will be invoiced, by the Commonwealth of Virginia Department of General Services, approximately 30 days after the corresponding purchase order is issued and payable 30 days after the invoice date. Any adjustments (increases/decreases) will be handled through purchase order changes.

Y. AVAILABILITY OF FUNDS

It is understood and agreed between the parties herein that the agency shall be bound hereunder only to the extent of the funds available or which may hereafter become available for the purpose of this agreement.

Z. SET ASIDES

This solicitation is set-aside for DMBE-certified small business participation only when designated "SET-ASIDE FOR SMALL BUSINESSES" in the solicitation. DMBE-certified small businesses are those businesses that hold current small business certification from the Virginia Department of Minority Business Enterprise. This shall not exclude DMBE-certified women-owned and minority-owned businesses when they have received the DMBE small business certification. For purposes of award, bidders/offerors shall be deemed small businesses if and only if they are certified as such by DMBE on the due date for receipt of bids/proposals.

J. PAYMENT (1 of 4)

PAYMENT (part 1 of 4): To Prime Contractor: a.) Invoices for items ordered, delivered and accepted shall be submitted by the contractor directly to the payment address shown on the purchase order/contract. All invoices shall show the state contract number and/or purchase order number; social security number (for individual contractors) or the federal employer identification number (for proprietorships, partnerships, and corporations). b.) Any payment terms requiring payment in less than 30 days will be regarded as requiring payment 30 days after invoice or delivery, whichever occurs last. This shall not affect offers of discounts for payment in less than 30 days, however. c.) All goods or services provided under this contract or purchase order, that are to be paid for with public funds, shall be billed by the contractor at the contract price, regardless of which public agency is being billed. d.) The following shall be deemed to be the date of payment: the date of postmark in all cases where payment is made by mail, or the date of offset when offset proceedings have been instituted as authorized under the Virginia Debt Collection Act. e.) Unreasonable Charges. Under certain emergency procurements and for most time and material purchases, final job costs cannot be accurately determined at the time orders are placed.(Continued on part 2)

J. PAYMENT (2 of 4)

PAYMENT (part 2 of 4): In such cases, contractors should be put on notice that final payment in full is contingent on a determination of reasonableness with respect to all invoiced charges. Charges which appear to be unreasonable will be researched and challenged, and that portion of the invoice held in abeyance until a settlement can be reached. Upon determining that invoiced charges are not reasonable, the Commonwealth shall promptly notify the contractor, in writing, as to those charges which it considers unreasonable and the basis for the determination. A contractor may not institute legal action unless a settlement cannot be reached within thirty (30) days of notification. The provisions of this section do not relieve an agency of its prompt payment obligations with respect to those charges which are not in dispute (Code of Virginia, § 2.2-4363). 2. To Subcontractors: a.) A contractor awarded a contract under this solicitation is hereby obligated: (1) To pay the subcontractor(s) within seven (7) days of the contractor's receipt of payment from the Commonwealth for the proportionate share of the payment received for work performed by the subcontractor(s) under the contract; or (2) To notify the agency and the subcontractor(s), in writing, of the contractor's intention to withhold payment and the reason. (continued on part 3)

J. PAYMENT (3 of 4)

PAYMENT (part 3 of 4): b.) The contractor is obligated to pay the subcontractor(s) interest at the rate of one percent per month (unless otherwise provided under the terms of the contract) on all amounts owed by the contractor that remain unpaid seven (7) days following receipt of payment from the Commonwealth, except for amounts withheld as stated in (2) above. The date of mailing of any payment by U. S. Mail is deemed to be payment to the addressee. These provisions apply to each sub-tier contractor performing under the primary contract. A contractor's obligation to pay an interest charge to a subcontractor may not be construed to be an obligation of the Commonwealth. 3.) Each prime contractor who wins an award in which provision of a SWAM procurement plan is a condition to the award, shall deliver to the contracting agency or institution, on or before request for final payment, evidence and certification of compliance (subject only to insubstantial shortfalls and to shortfalls arising from

subcontractor default) with the SWAM procurement plan. Final payment under the contract in question may be withheld until such certification is delivered and, if necessary, confirmed by the agency or institution, or other appropriate penalties may be assessed in lieu of withholding such payment.

J. PAYMENT (4 of 4)

PAYMENT (part 4 of 4): The Commonwealth of Virginia encourages contractors and subcontractors to accept electronic and credit card payments.

AA. BID PRICE CURRENCY:

BID PRICE CURRENCY: Unless stated otherwise in the solicitation, bidders/offerors shall state bid/offer prices in US dollars.

BB. BUSINESS AUTHORIZATION

AUTHORIZATION TO CONDUCT BUSINESS IN THE COMMONWEALTH: A contractor organized as a stock or nonstock corporation, limited liability company, business trust, or limited partnership or registered as a registered limited liability partnership shall be authorized to transact business in the Commonwealth as a domestic or foreign business entity if so required by Title 13.1 or Title 50 of the Code of Virginia or as otherwise required by law. Any business entity described above that enters into a contract with a public body pursuant to the Virginia Public Procurement Act shall not allow its existence to lapse or its certificate of authority or registration to transact business in the Commonwealth, if so required under Title 13.1 or Title 50, to be revoked or cancelled at any time during the term of the contract. A public body may void any contract with a business entity if the business entity fails to remain in compliance with the provisions of this section.

SPECIAL TERMS AND CONDITIONS

<u>ADVERTISING</u>: In the event a contract is awarded for supplies, equipment, or services resulting from this bid, no indication of such sales or services to the Commonwealth of Virginia will be used in product literature or advertising. The vendor shall not state in any of its advertising or product literature that the Commonwealth of Virginia has purchased or uses any of its products or services, and the vendor shall not include the Commonwealth of Virginia in any client list in advertising and promotional materials.

AWARD: This Contract will be awarded to a single vendor, on a grand total basis to the lowest responsive and responsible bidder. The purchasing office reserves the right to conduct any test it may deem advisable and to make all evaluation. The Commonwealth also reserves the right to reject any or all bids, in whole or in part, to waive informalities and to delete items prior to making the award, whenever it is deemed in the sole opinion of the procuring public body to be in its best interest. In case of arithmetic errors, the unit price will govern. If cash discount for prompt payment is offered, it must be clearly shown. Discounts for prompt payment will not be considered in making awards.

<u>ADDITIONAL INFORMATION</u>: The Commonwealth reserves the right to ask any bidder to submit information missing from its bid, to clarify its bid, and to submit additional information which the Commonwealth deems desirable.

AUDIT: The vendor shall retain all books, records, and other documents relative to this contract for five (5) years after final payment, or until audited by the Commonwealth of Virginia, whichever is sooner. The

agency, its authorized agents, and/or state auditors shall have full access to and the right to examine any of said materials during said period.

<u>BID ACCEPTANCE PERIOD</u>: Any bid in response to this solicitation shall be valid for <u>90</u> days. At the end of the <u>90</u> days the bid may be withdrawn at the written request of the bidder. If the bid is not withdrawn at that time it remains in effect until an award is made or the solicitation is canceled.

CANCELLATION OF CONTRACT: The purchasing agency reserves the right to cancel and terminate any resulting contract, in part or in whole, without penalty, upon 60 days written notice to the vendor. In the event the initial contract period is for more than 12 months, the resulting contract may be terminated by either party, without penalty, after the initial 12 months of the contract period upon 60 days written notice to the other party. Any contract cancellation notice shall not relieve the Vendor of the obligation to deliver and/or perform on all outstanding orders issued prior to the effective date of cancellation.

<u>CONFIDENTIALLY OF INFORMATION</u>: Awarded vendor will recognize all privacy regulations, to include but not be limited to, the U.S. Department of Health & Human Services Health Insurance Portability and Accountability Act of 1996 (HIPAA) and Patient Safety and Quality Improvement Act of 2005.

The Vendor assures that information and data obtained as to personal facts and circumstances related to patients or clients will be collected and held confidential, during and following the term of this agreement, and will not be divulged without the individual's and the agency's written consent and only in accordance with federal law or the Code of Virginia. Vendors who utilize, access, or store personally identifiable information as part of the performance of a contract are required to safeguard this information and immediately notify the agency of any breach or suspected breach in the securing of such information. Vendors shall allow the agency to both participate in the investigation of incidents and exercise control over decisions regarding external reporting. Vendors and their employees working on this project may be required to sign a confidentiality statement.

<u>CONTACT INFORMATION</u>: Provided by Vendor as <u>Attachment A - Bidder Data Sheet</u> in bid response.

CONTINUITY OF SERVICES: The Vendor recognizes that the services under this contract are vital to the Commonwealth and must be continued without interruption and that, upon contract expiration, a successor, either the Commonwealth or another vendor, may continue them. The Vendor agrees: 1. To exercise its best efforts and cooperation to effect an orderly and efficient transition to a successor; 2. To make all Agency owned facilities, equipment, and data available to any successor at an appropriate time prior to the expiration of the contract to facilitate transition to successor; and 3. That the Agency Contracting Officer shall have final authority to resolve disputes related to the transition of the contract from the vendor to its successor.

The vendor shall, upon written notice from the contract Officer, furnish phase-in/phase-out services for up to ninety (90) days after this contract expires and shall negotiate in good faith a plan with the successor to execute the phase-in/phase-out services. This plan shall be subject to the contract Officer's approval.

The Vendor shall be reimbursed for all reasonable, pre-approved phase-in/phase-out costs (i.e., costs incurred within the agreed period after contract expiration that result from phase-in, phase-out operations) and a fee (profit) not to exceed a pro rata portion of the fee (profit) under this contract. All phase-in/phase-out work fees must be approved by the Contract Officer in writing prior to commencement of said work.

CONTRACT TERM: The initial term of this contract will be for a two (2) year period beginning approximately January 1, 2012 through December 31, 2014.

CONTRACT RENEWAL: This contract may be renewed by the Commonwealth upon written agreement of both parties for three (3) optional one (1) year periods, under the terms of the current contract, and at a reasonable time (approximately 90 days) prior to the expiration.

<u>DELIVERY SERVICE</u>: Delivery of all requested contract items shall be made within 10 calendar days after receipt of purchase order. All orders shall be shipped directly to DCLS. Contractor shall communicate to the ordering agency by telephone any situation which will delay delivery beyond 10 days from receipt of order, indicating which items are back-ordered and when delivery will be completed. The vendor shall carry an adequate stock to insure such delivery service for the duration of the contract.

EQUIPMENT: Bidders shall submit prices based on a rental/loaner option for equipment. The contractor shall supply **new and most current equipment available** at no charge to the Commonwealth. Equipment may be added to or removed from this contract at anytime, so long as performance, reliability, and service are not reduced. Contractor may add or remove equipment by submitting, with its serial number and stating what action is being taken and when. Title shall at all times remain with the contractor. Maintenance is the responsibility of the title holder. The user will be responsible for all supplies and consumable. As an attachment to your response, please list equipment to be supplied for this contract by clearly identifying the equipment (see page 4 for chart), attach descriptive literature, catalog cuts, and/or specifications.

eVA BUSINESS-TO-GOVERNMENT CONTRACTS AND ORDERS

It is anticipated that the contract will result in multiple purchase orders (i.e., one for each delivery requirement) with the eVA transaction fee specified below assessed for each order."

- For orders issued prior to August 16, 2006, the Vendor Transaction Fee is 1%, capped at a maximum of \$500 per order.
- b. For orders issued August 16, 2006 through July 1, 2011, the Vendor Transaction Fee is:
 - (i) DMBE-certified Small Businesses: 1% capped at \$500 per order.
 - (ii) Businesses that are not DMBE-certified Small Businesses: 1% capped at \$1,500 per order.
- c. For orders issued July 1, 2011, through June 30, 2012, the Vendor Transaction Fee is:
 - (i) DMBE-certified Small Businesses: 0.75%, Capped at \$500 per order.
 - (ii) Businesses that are not DMBE-certified Small Businesses: 0.75%, Capped at \$1,500 per order.
- d. For orders issued July 1, 2012, and after, the Vendor Transaction Fee is:
 - (i) DMBE-certified Small Businesses: 1%, Capped at \$500 per order.
 - (ii) Businesses that are not DMBE-certified Small businesses: 1%, capped at \$1,500 per order.

The specified vendor transaction fee will be invoiced, by the Commonwealth of Virginia, Department of General Services, approximately 30 days after the corresponding purchase order is issued and payable 30 days after the invoice date. Any adjustments (increases/decreases) will be handled through purchase order changes.

The eVA Internet electronic procurement solution, website portal www.eva.virginia.gov, streamlines and automates government purchasing activities in the Commonwealth. The portal is the gateway for vendors to conduct business with state agencies and public bodies.

Vendors desiring to provide goods and/or services to the Commonwealth shall participate in the eVA Internet e-procurement solution and agree to comply with the following: If this solicitation is for a term contract, failure to provide an electronic catalog (price list) or index page catalog for items awarded will be just cause for the Commonwealth to reject your bid or terminate this contract for default. The format of this electronic catalog shall conform to the eVA Catalog Interchange Format (CIF) Specification that can be accessed and downloaded from www.eva.virginia.gov. Vendors should email Catalog or Index page information to eVA-catalog-manager@dgs.virginia.gov.

EXTRA CHARGES NOT ALLOWED: The bid price shall be for complete installation ready for the Commonwealth's use, and shall include all applicable freight and installation charges; extra charges will not be allowed.

INSTRUMENTS/CONSUMABLES: Bidders shall submit with their bid, a list of consumables not required but supplied if needed to operate their system (see page 4 for chart). If a charge is applicable, please note that charge.

LABELING OF HAZARDOUS SUBSTANCES: If the items or products requested by this solicitation are "Hazardous Substances" as defined by § 1261 of Title 15 of the United States Code (U.S.C.) or "Pesticides" as defined in § 136 of Title 7 of the United States Code, then the bidder, by submitting his bid, certifies and warrants that the items or products to be delivered under this contract shall be properly labeled as required by the foregoing sections and that by delivering the items or products the bidder does not violate any of the prohibitions of Title 15 U.S.C. § 1263 or Title 7 U.S.C. § 136.

MATERIAL SAFETY DATA SHEETS: If applicable, Material Safety Data Sheets and descriptive literature shall be provided with the bid for each chemical and/or compound offered. Failure on the part of the bidder to submit such data sheets may be cause for declaring the bid as nonresponsive.

MINIMUM ORDER: Minimum Orders are set at \$100.00. Orders will be F.O.B. Destination to ordering agency within the Commonwealth of Virginia. For orders of less than \$100.00 the vendor will be permitted to add actual transportation cost (prepaid) to invoice for payment, or the agency may purchase such orders off contract from other sources. Partial shipments of less than minimum order value which are made at the option of the vendor shall be made F.O.B. Destinations with no transportation charges added. If at the agency's request shipments are below the minimum order value, the vendor may add actual transportation to invoice for payment.

ORDER PLACEMENT/METHOD: To the maximum extent possible, purchase orders shall be submitted to the contractor via the Commonwealth of Virginia's electronic procurement system, also known as eVA. The orders will be governed by this agreement and the terms and conditions contained in the separate agreement for participation in eVA executed by the contractor. The Commonwealth requires contractors to accept orders via the eVA ordering system.

PRICE ESCALATION / DEESCALATION: Price adjustments may be permitted only for changes in the Vendor's cost of materials based on the current market for this or similar products. Consumers Price Indices, Producers Price Indices or other appropriate indices as approved by the Division of Purchases and Supply, will be used as a quide to determine price increases or decreases. No price increases will be authorized for 365 calendar days after the effective date of the contract. Price escalation may be permitted only at the end of this period and each 365 days thereafter and only where verified to the satisfaction of the purchasing office. However, "across the board" price decreases are subject to implementation at any time and shall be immediately conveyed to the Commonwealth. Vendor shall give not less than 30 days advance notice of any price increase to the purchasing office. Any approved price changes will be effective only at the beginning of the calendar month following the end of the full 30 day notification period. The Vendor shall document the amount and proposed effective date of any general change in the price of materials. Documentation shall be supplied with the Vendor's request for increase which will: (1) verify that the requested price increase is general in scope and not applicable just to the Commonwealth of Virginia; and (2) verify the amount or percentage of increase which is being passed on to the Vendor by the Vendor's suppliers. The purchasing office will notify the using agencies and Vendor in writing of the effective date of any increase which it approves. However, the Vendor shall fill all purchase orders received prior to the effective date of the price adjustment at the old contract prices. The Vendor is further advised that decreases which affect the cost of materials are required to be communicated immediately to the purchasing office.

<u>PURCHASE CARD INFO</u>: DCLS may make purchases using a major credit card. Currently the Commonwealth uses Bank of America - VISA. Please list the major credit cards that will be accepted by your company under any resulting contract. . <u>VISA, American Express and MASTERCARD accepted.</u>

Acceptance of Small Purchase Charge Card: Purchasing charge cards offer State agencies and Institutions the opportunity to streamline their procedures for procuring and paying for small dollar goods and services (typically \$5,000 and under). Vendors responding to this solicitation should note that acceptance of payment by purchase card is the preferred method of payment by the Commonwealth.

Payment for orders issued against the contract resulting from this solicitation must allow for the Purchase Order Number to be passed at the time of charge so that the Purchase Order Number is received by the card platform and passed to the Card provider. This can be accomplished by vendors establishing their card account at **Level 2**, **which is mandatory or Level 3 which is optional**. Information on the various levels for the Bank of America – VISA is indicated below.

Charge Card Levels:

The amount of data passed for each charge card payment depends on the level at which the charge card is established. The levels are delineated below. The preferred level by the Commonwealth is Level 2.

Level 1

Vendors provide basic credit card purchase information, including but not limited to the data listed below. By passing "Basic Data", the vendor has a standard interchange cost.

- Supplier Name
- Merchant Category Code
- Date
- Total Purchase Amount

Level 2

Vendors provide additional information to the Level 1 elements, including, but not limited to the data listed below. By passing level 2 detail, the vendor will receive lower interchange costs. Level 2 is **mandatory** for any vendors who do business with the Commonwealth of Virginia and accept Bank of America - VISA.

- Customer Code (PCO Number from eVA)
- Vendor Tax ID

Level 3

Vendors provide line item detail, in addition to the Level 1 and Level 2 elements, including, but not limited to the data listed below. By passing Level 3 (which is optional) data which is considered Superior data, the vendor will receive the lowest interchange costs.

- Item Description
- Item Quantity
- Item Unit of Measure
- Product Code
- Freight Amount
- Extended line Item Amount

For more information regarding the Commonwealth of Virginia, Department of Accounts (DOA) Small Purchase Charge Card Program, visit the website:

http://www.doa.virginia.gov/General Accounting/Charge Card/Charge Card Main.cfm

<u>PURCHASE VOLUME REPORT</u>: The vendor shall furnish quarterly volume reports (January, February and March=1st quarter; April, May, and June=2nd quarter; July, August, and September=3rd quarter; and October, November, and December=4th quarter) within 15 days of the end of each quarter of the sales made under this contract. Report shall list item(s) and or services performed during the previous quarter along with the order number and dollar value. These reports shall include: item purchased, date purchased, agency, quantity, each price, extended price, and eVA purchase order number.

QUANTITIES: Quantities set forth in this solicitation are estimates only, and the contractor shall supply at bid prices actual quantities as ordered, regardless of whether such total quantities are more or less than those shown.

<u>\$5.2-</u> 4311.2 subsection B, a bidder or offeror organized or authorized to transact business in the Commonwealth pursuant to Title 13.1 or Title 50 is required to include in its bid or proposal the identification number issued to it by the State Corporation Commission (SCC). Any bidder or offeror that is not required to be authorized to transact business in the Commonwealth as a foreign business entity under Title 13.1 or Title 50 or as otherwise required by law is required to include in its bid or proposal a statement describing why the bidder or offeror is not required to be so authorized. Indicate the above information on the SCC Form provided. Contractor agrees that the process by which compliance with Titles 13.1 and 50 is checked during the solicitation stage (including without limitation the SCC Form provided) is streamlined and not definitive, and the Commonwealth's use and acceptance of such form, or its acceptance of Contractor's statement describing why the bidder or offeror was not legally required to be authorized to transact business in the Commonwealth, shall not be conclusive of the issue and shall not be relied upon by the Contractor as demonstrating compliance. (Complete Attachment B – STATE CORPORATION COMMISSION FORM.) PerkinElmer Health Sciences, Inc. SCC Number: F1608787.

SPECIFICATIONS

** PerkinElmer exceptions have been noted within the Specifications in <u>BLUE</u> and are agreed upon by DCLS.

The Specifications cover the reagent solutions, equipment and any other special materials needed for measuring the neonatal thyroxine (t4), thyroid stimulating hormone (TSH) for the detection of Congenital Hypothyroidism, as well as screening for 17 Hydroxyprogesterone (170HP) for the detection of Congenital Adrenal Hyperplasia in infants – using immunoassay technology.

A. Application Specifications and Standards

All HHS and FDA Regulations on immunoassay kits in effect on the date of the Invitation for Bids shall apply. Human blood used in the preparations of standards and controls must be negative for the antibody to HTLV-III (HIV) and non-reactive for Hepatitis B-surface antigen (HbsAg) when tested with licensed reagents.

B. Specifications

T4, TSH, and CAH kits must contain all necessary reagents and materials needed to measure the concentration of thyroxine, thyroid stimulating hormone or 17 hydroxyprogesterone in neonatal dried blood specimens. The components in these kits must include the following:

- Standards and Controls. These two components must conform to standards set by the Clinical Laboratory Standards Institute (CLSI Vol. 5, LA4-A5), as well as guidelines within CLIA of '88.
 - a. All T4 concentrations will be expressed as ug/dL of serum and are equivalent to a single1/8" disk punched from Whatman #903 filter paper or equivalent.
 - b. All TSH concentrations will be expressed in uU/mL in blood and/or serum and are equivalent to a single 1/8" disk punched from Whatman #903 filter paper or equivalent. PerkinElmer exception: "The filter paper vendor could begin to ship another lot at any time during the contract year". Extended clarification provided by PerkinElmer to read: "When a filter paper lot changes, the following parameters are checked: 1) Blood spot size test Blood spot size test is performed and sampling is performed by random checks using the following dispensing volumes: 40, 50, 60, and 70 uL. 2) Blood absorption test Blood absorption test is performed and sampling is performed by random checks; acceptable absorption time is between 5-30 seconds".
 - c. All 170HP concentrations will be expressed as ng/mL of serum and are equivalent to a single 1/8" disk punched from Whatman #903 filter paper or equivalent.
 - d. All standards and controls must be human dried whole blood spots on Whatman #903 filter paper or equivalent. The same lot of the Whatman #903 or equivalent must be used during the contract year.
 - e. All standards and controls must be standardized for accuracy using CDC Quality Control Spots for Neonatal Hypothyroidism. The vendor must submit written documentation of their precision and accuracy for measuring CDC quality control dried blood spots. PerkinElmer exception: "The CDC has communicated to reagent manufacturers that they should not use CDC controls to standardize their assays. CDC controls are meant to be used as external controls and independent from all methods". PerkinElmer has supplied calibration certificates for the methods used to calibrate both the AutoDELFIA and GSP neonatal TSH and Neonatal T4 assays.
 - f. Dried blood spot standards must be provided with each T4 kit. The T4 concentration of these standards must range from 0 to 25 ug/dL of serum.
 - g. Dried blood spot standards must be provided with each TSH kit. The TSH concentration of these standards must range from 2.0to >600uU/mL in blood and/or serum.
 - h. Dried blood spot standards must be provided with each 17 OHP kit. The 170HP concentration of these standards must range from 0ng/mL to 300ng/mL in blood and/or serum.
 - A minimum of three blood spot controls must be provided in the T4 kit at low (2-5ug/dL), mid-range (6-10ug/dL), and normal (11-25ug/dL) T4 concentrations.
 - j. A minimum of three blood spot controls must be provided in the TSH kit at normal (0-15uU/mL), grey zone (20-45uU/mL), and high (>45uU/mL) TSH concentrations.
 - k. A minimum of three blood spot controls must be provided in the 170HP kit at low (0-10ng/mL), mid-range (25-35ng/mL), and high (>70ng/mL) 170HP concentrations.
- 2. Sufficient quantity of each reagent must be supplied to allow for priming pipetters, testing of washers, and parallel testing of kits for compliance (- approximately 5-10%).
- 3. Test kits must be compatible with the following existing equipment used for sample preparation. (The use of micro titer plates is required).
 - a. BSD Punch Machine.
 - b. Delfia micro plate bench top punch.
- 4. Instrumentation/Computerization

- a. Testing instrumentation must include all computer equipment, printers, and software necessary to analyze samples, capture workload data, and maintain quality control information.
- b. Instrumentation must provide a walk-away solution with the capability to handle volumes up to 12 micro titer plates in a run, with a rapid completion time.
- c. The vendor's software should be compatible with common window-based tools and must have software in place to immediately interface with the NBS STARLIMS software application at the time of bid submission.
- 5. Shipments must be delivered with a frequency that will allow the Lab to store all kit components in available refrigeration units within the Newborn Screening Lab area. Reagents must demonstrate adequate stability, when in use.
- Each shipment must be accompanied by written documentation showing that all quality control parameters have been met. Results and expected ranges of quality control blood spots must be provided.

7. Procedures

- Procedures for performing each test must be included in the kit, as a package insert.
- b. The protocol for T4 and CAH testing must allow for the completion of 1,000 samples within an 8-hour workday.
- c. The protocol for TSH testing must allow for the completion of 300 samples within an 8-hour workday.
- 8. All lots of reagents will be assayed in the laboratory to verify compliance to the accompanying parameters. Lots, which fail to comply, must be replaced with an acceptable lot within 24 hours of notification.
- Technical assistance must be available in the field and by telephone between the hours of 8:00 a.m. and 5:00 p.m. – Eastern Standard Time, Monday through Saturday Friday. When phone assistance is insufficient, the vendor must be capable of providing on-site response by the next workday.
- 10. The vendor must be capable of providing replacement parts and/or loaner equipment, with next day delivery, to minimize laboratory downtime.
- 11. <u>Bid Sample</u>: Within two weeks of DCLS' request, the bidder shall provide, without charge to the Commonwealth, sample kits and necessary equipment for each item bid to be evaluated on-site by the Virginia Newborn Screening Laboratory.
- 12. <u>MSDS Information</u>: Each vendor is required to provide MSDS documentation for all reagents used in the T4 and TSH test kits. Kits containing carcinogenic or otherwise environmentally hazardous reagents may be removed from consideration.
- 13. <u>Reagent Rental Option</u>: Each vendor must include in their bid, the option to provide test kits, consumables, equipment, software and maintenance as a "reagent rental" package.
- 14. <u>FDA Approval</u>: The vendor must be able to verify FDA approval for all kits, upon bid submission.
- 15. Evaluation of all test kits shall be performed by DCLS personnel within their normal work environment. Testing that requires prolonged incubations or any other parameter that does not conform to the DCLS/NBS workflow, may not be considered. The bidder is responsible to provide sufficient descriptive literature, testing procedures and detailed

- specifications to enable DCLS to determine if the products offered meet the requirements of the bid and the work schedule of the DCLS/NBS Laboratory.
- 16. The vendor of contract must provide at no charge to the Commonwealth, on-site training for laboratory staff. This training must allow for individual and small group training for a staff of 15.

Equipment

Bidders shall submit prices based on the Rental/Loaner option. The Commonwealth will review the bids and make an award that is deemed to be in the best interest of the Commonwealth.

(Rental/Loaner) – The vendor shall supply equipment at no charge to the Commonwealth. All automated equipment required to prepare reagents, process and test samples must be included in the reagent kit pricing. Equipment may be added to or removed from the awarded Contract at anytime, so long as performance, reliability and service are not reduced. Title shall at all times remain with the vendor. Maintenance is the responsibility of the title holder. The using agency will be responsible for all supplies and consumable. The vendor may add or remove equipment by submitting a letter to the using agency with a copy to the Contract Officer, with a description of the equipment, with its serial number and stating what action is being taken and when. Provide descriptive literature, catalog cuts, and/or specifications. Please list below equipment to be supplied for this contract.

Quantity	Serial Number	<u>Description</u>
2		2021-0010: Genetic Screening Processors
2		2011-0040: Wallace Lab. Laser Printers
2		UPSAP200: Unite4rruptable Power Supplies